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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Mailed

12 Sunnen Drive, Suite 122
St. Louis, Missouri 63143-3800
(314) 645-1167, (314) 645-2969 FAX

September 16, 1999

# WARNING LETTER

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Carl Simon
Owner
Carl Simon Farm
11202 Cemetery Road
Farley, IA 52046

Re: STL-99-06

Dear Mr. Simon:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on 5/26/1999 and 6/1,15/1999 by a Food and Drug Administration Investigator has revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Acts) as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On April 8, 1999, you sold a Holstein cow (identified by a back tag number 0406) for slaughter as human food at [redacted] This cow was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this cow revealed erythromycin in the kidney at 0.34 parts per million (ppm). Presently, the tolerance level has not been established for erythromycin in the uncooked edible kidney tissues of cattle.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions ... whereby it may have been rendered injurious to health." As it applies in this case, "insanitary condition" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are inadequate and medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

2. You lack an adequate system for determining the medication status of animals you offer for slaughter.

3. You lack an adequate inventory system for determining the quantities of drugs used to medicate yours cows and calves.

You are adulterating the drug erythromycin injection contained in the product [redacted] which you use to medicate your cow within the meaning of Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) since it is not being used in conformance with approved labeling. You completely disregard the [redacted] warning statement, which prohibits its use in female dairy cattle greater than 20 months of age or in other words, a lactating dairy cow; or you did not follow the provisions for extra-label drug use in animals as set forth in 21 CFR 530 under Animal Medicinal Drug Use Clarification Act of 1994 (the AMDUCA).

Failure to comply with the label instructions on a drug presents the likely possibility that illegal residues will occur and makes the drug unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

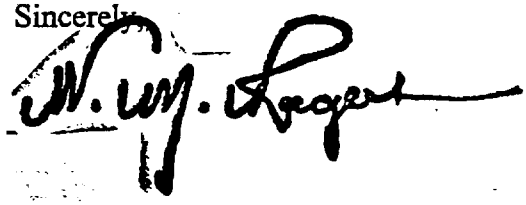
Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you offered an adulterated animal for sale to a slaughterhouse where it was held for sale in interstate commerce is sufficient to make you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence.

If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made. Your response should be sent to Andrew H. Paeng, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
Director
Kansas City District